K061996

OCT - 3 2006

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

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Date: June 12, 2006

807.92(a)(2)

Trade Name: Sandman Pocket

Common Name: Ventilatory Effort Recorder

Classification Name(s): Ventilatory Effort Recorder

Classification Number: MNR

807.92(a)(3)

Predicate Device(s)

Nellcor Puritan Bennett Inc. Respironics, IN	SUZANNE Alice 5	K990565 K040595

Additional Substantial Equivalence Information is provided in the following Substantial Equivalence Comparison Table.

807.92 (a)(4)

Device Description

The *Sandman Pocket* is a physiological data recorder that is part of a polysomnography system. It consists of two units: the **Recorder Unit**, which stores the data and sends it to a USB port, and **Headbox Unit**, which is the connection point for all patient sensors with the exception of the Nellcor Puritan Bennett oximetry probe.

The role of the *Sandman Pocket* is only to capture the data and pass it to the host with the necessary accuracy and reliability according to the product and communication control specifications.

A fundamental characteristic of the *Sandman Pocket* is the ability to be an ambulatory/portable physiological data recorder. Because of its small size and light weight (about 210 grams including the battery), the system is compact and durable.

The **Headbox Unit** is used for connecting patient electrodes and sensors. It includes Bipolar channels, pressure sensors, power supply for a dedicated body position sensor, an abdomen sensor, a chest sensor, a snore sensor and a thermistor. The patient inputs are isolated with a CF type isolation level. The Sandman Pocket device is provided without standard sensors. The system builder should integrate the device with FDA cleared Nellcor Puritan Bennett sensors only and specified for the usage with NELL-1 module.

The **Headbox Unit** captures the biological signals from the human body surface through specialized sensors and electrodes, while the **Recorder Unit** amplifies the very low electrical signal and filters the signals to make an optimal ANALOG to DIGITAL conversion. The data, once converted in numerical form, are sent to a host computer for review and analysis. The host can "program" the amplifier behavior by setting the sampling frequency and the dynamic range allowed and so on.

The host computer reads the acquired data through a dedicated interchange protocol, and allows a clinician to analyze the data using sleep review analysis software, provided by the end user or system builder. The clinician must use an electrically isolated computer (with a medical grade isolation transformer or medical grade power supply) or battery-supplied laptop when the Sandman Pocket device is connected to the host PC and the patient is connected to the Sandman Pocket Headbox.

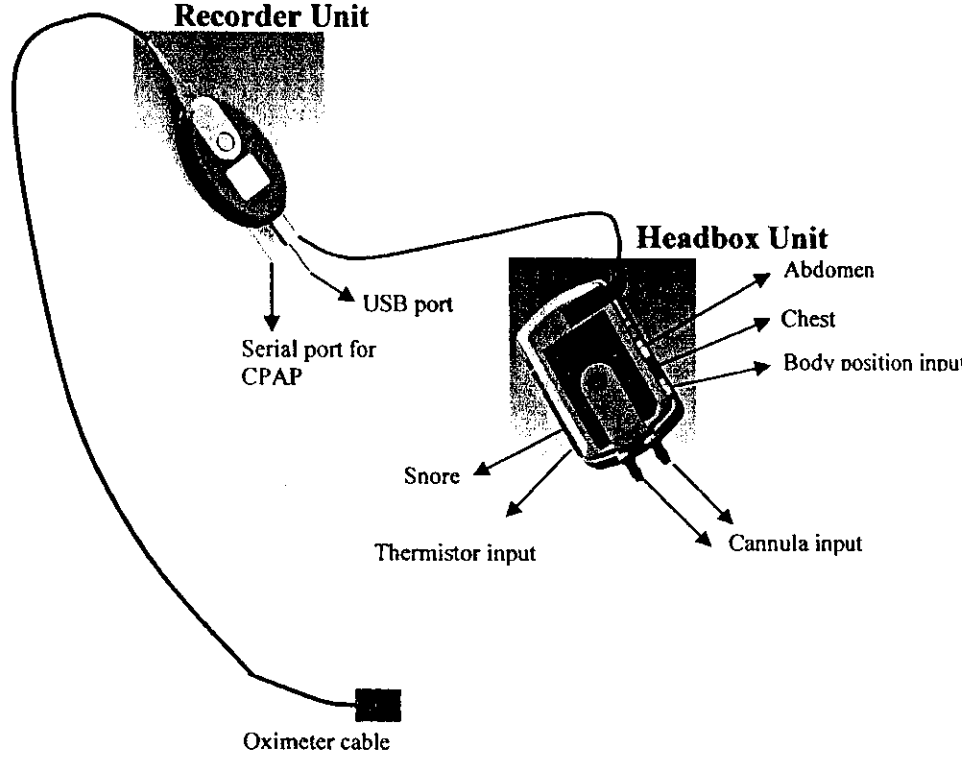
The *Sandman Pocket* system is not in any way involved in the data management performed by the host.
The host computer must operate using one of the following Operating System:
Microsoft Windows 98 / ME / NT / 2K / XP.

The device has a built-in impedance meter. This function allows the clinician to check the electrode contact impedance and display the results of the check on the display. The

display is located in the Recorder Unit, while the circuitry controlling the impedance meter is located in the Headbox Unit.

The *Sandman Pocket* can be powered through 3 Alkaline 1.5V standard non rechargeable batteries or via the USB cable. The user is recommended to use a medical grade type PC.

The *Sandman Pocket* system consists of two interconnected units: the Headbox Unit and the Recorder Unit.



SANDMAN POCKET System Connection Diagram

The **Headbox Unit** has the following functions:

- Physically connects the source of signals (the patient) to the amplifier.
- Provide impedance testing capabilities
- Provide Analog to Digital (A/D) conversion

The **Recorder Unit** has the following functions:

- Amplify and isolate signals coming from the electrodes
- Reference input channels
- Generate calibration pulse
- Provide dynamic range (gain), sampling rate and active channels selection
- Performs antialiasing filtering for optimal Analog to Digital conversion
- Provide, when requested, the Pulse Transition Time (PTT) calculation.
- Send the digital data through the USB interface to the host
- Provide the Oximeter option
- Manage the display
- Manage the Time
- Manage the batteries power supply

807.92(a)(5)

Intended Use(s)

The *Sandman Pocket* is intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. The Sandman Pocket is intended for pediatric through adult patient populations, and can be used in either home or hospital environments.

The Sandman Pocket is not intended for use as life supporting equipment such, as a vital sign monitoring in an intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor.
The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician.

Technological Characteristics
Substantial Equivalence Comparison Table

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Regulatory			
Device class	Class II	Class II	Class II
Product code	MNR	GWQ	MNR
Device type	Ventilator Effort Recorder	Electroencephalograph	Ventilator Effort Recorder
Regulation Number	868.2375	882.1400	868.2375

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Labelling			
Intended use	Intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders	Intended to record, display and print physiological information to clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adult or infant patients require the documentation of various sleep or other physiological disorders. This device does not provide alarms and is not intended for use as an automated apnea monitor.	Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. For use in either home or hospital environments with a pediatric through adult patient population. This device does not provide alarms and is not intended for use as an automated apnea monitor
Target population	Pediatric through adult (excluding neonates and infants)	Pediatric through adult (including all pediatric subpopulations)	Pediatric through adult (including all pediatric subpopulations)
Environment of use	Hospital and home	Hospitals, institutions, sleep centers, or other test environments.	Hospital and home

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Warnings	Items related to sensor irritation, strangulation avoidance and off-label use.	Items related to sensor irritation, strangulation avoidance, and off-label use.	Items related to sensor irritation, strangulation avoidance and off-label use.
Contraindications	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment.	Items related to design and indicated use limitations, such as not for use in the presences of flammable substances or anesthetic mixtures with air oxygen or nitrous oxide, defibrillation, and MRI equipment, and not for use as automated apnea monitor or a continuous monitor.	Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment. The Sandman Pocket is not intended for use as life support equipment such as a vital sign monitoring in intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor. The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.
Prescription status	Available only on the order of a physician.	Available only on the order of a physician.	Available only on the order of a physician.

Product Characteristic	***Suzanne*** **(Predicate Device)** **Nellcor Puritan Bennet** **K990565**	***Alice 5*** **(Predicate Device)** **Respironics** **K040595**	***Sandman Pocket*** **(submission device)** **EB Neuro** **Via this Submission**
Service instructions	No field service allowed.	No field service allowed.	No field service allowed.
Design			
Communication Interfaces	Physiological signals are sent to the Slow Wave and Fast Wave headbox through the sensor cables. The Slow Wave and Fast Wave headboxes sends the data to the Recorder Plus module where the data is stored either to a flash memory card or to a PC via a fiber optic interface.	Physiological signals are sent from the patient sensors to the headbox through the sensor cables. The data is sampled and sent to the base station where it is stored on a disk until it is sent through an Ethernet connection to a Host PC.	Physiological signals are sent from the patient sensors to the amplifier box through the sensor cables. The amplifier box sends the data to the recorder where the data is stored in flash memory in both attended and unattended studies. During attended studies, the data is also transmitted to a computer in real-time via a USB cable. After unattended studies, data can be downloaded from the recorder using a USB cable.
Microprocessor	Siemens 80C537 12 MHz	Unknown	Texas Instruments TMS320UC5402 on recorder Texas Instruments MSP430F169 on headbox
A/D Resolution	12 bit	16 bit	16 bit

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Data recording	On PCMCIA card, magnetic disk or optical disk (via a personal computer).	Computer hard drive, compact disc, or transferred via Ethernet connection to a Host PC.	On internal NAND flash chip
Configuration	Desktop and wearable	Desktop only	Wearable
Amount of memory required for a typical 8 hour study.	20 MB	600 MB without audio/ video 6 GB with audio/video NOTE: Alice 5 can collect up to 21 neurological channels. These channels are recorded at very high sampling rates. In addition, Alice 5 records video at very high frame rates with no compression. These two factors contribute to the large study size. All data are stored to computer hard disk.	28 MB

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Sampling rate	Slow waves : 12 samples/s Fast waves : 120 samples/s	Neurological channels 2000 samples/s	Fast waves: For example, ECG programmable up to 2048 sample/s Medium waves: For example, EMG, EOG, Snore programmable up to 1024 sample/s Slow waves: For example, airflow, respiratory effort, body position programmable up to 256 sample/s
Power	Battery powered (internal) or Medical Grade AC-DC Power Supply	Medical grade AC Power Supply	Battery powered or USB powered
Sensors	Commercially available sensors only	Commercially available sensors only	FDA Cleared sensors only

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Performances			
Maximum number of channels	35	55	22
Recording channels			
EEG	Yes	Yes	Yes
EOG	Yes	Yes	Yes
EMG	Yes	Yes	Yes
ECG	Yes	Yes	Yes
Respiratory efforts	Yes	Yes	Yes
Airflow	Yes	Yes	Yes
Ambient sounds	Yes	Yes	No
Body position	Yes - internal	Yes - external	Yes - external
Ambient light	Yes - internal	No	No
SpO_2	Yes - internal	Yes - internal	Yes - internal
Pulse rate	Yes - internal	Yes - internal	Yes - internal
Plethysmograph	No	Yes	Yes
Differential pressure	Yes - internal	Yes - external	Yes - internal
Actimeter	No	Yes	No
Derived channel	N/A	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R wave on the EKG and the peak flow on the plethysmogram. RR Interval – Measurement of the period of time between two consecutive R waves on the EKG. Displays as a real-time beat-to-beat heart rate calculation.	Pulse Transit Time (PTT) – A calculation of the time between the occurrence of the R-wave on the EKG and 50% ascending slope on the plethysmogram. Heart rate – Derived from the ECG channel

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Passbands			
EEG	0.625 to 18 Hz	Neurological Channels	0.1 to 135 Hz
EOG	0.625 to 18 Hz	0.32 to 106 Hz	0.1 to 135 Hz
EMG	0.625 to 18 Hz		0.1 to 135 Hz
ECG	0.625 to 18 Hz		0.1 to 135 Hz
Respiratory efforts	0.055 to 1.25 Hz		0.1 to 45 Hz
Airflow	0.1 to 1.3 Hz		0.015 to 10 Hz
Ambient sounds	None		None
Pressure sensor	0 to 175 Hz		DC to 15 Hz
SpO_2	NPB proprietary		NPB proprietary
Pulse rate	NPB proprietary		NPB proprietary

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CPAP (Continuous Positive Airway Pressure)	*Suzanne* supports all models of CPAP devices because the CPAP device connections were air-based rather than electrically based. Using a pneumotachograph kit, users could connect hoses and adapters to the CPAP device and the flow and pressure nipples on the *Suzanne* slow wave headbox to measure CPAP airflow and/or air pressure at the mask out-take during nasal CPAP/Bi-level titration.	*Alice 5* supports the use of all Respironics lab therapy devices: Aria LX BiPAP Pro Duet LX Harmony HeartPAP REMStar Auto REMStar Pro REMStar Pro with C-Flex Synchrony Virtuoso LX	*Sandman Pocket* stores data from Nellcor Puritan Bennett GK420E, GK425, and GK425ST CPAP devices. When the recorder is also connected to the host computer, the *Sandman Pocket* not only stores data in the on-board memory, but also acts as a passive bridge between the aforementioned GK CPAP and the host computer by receiving data streams from the CPAP and transmitting the data streams to the host computer and vice versa. When the *Sandman Pocket* is connected to a third party CPAP device and a host computer, *Sandman Pocket* acts as a passive bridge between the third party CPAP device and the computer by receiving data streams from the CPAP and transmitting the data streams to the host computer and vice versa. Alternatively, *Sandman Pocket* may also handle CPAP device connections in the same manner as Suzanne.

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Mechanical safety	Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1 CSA C22.2 No. 601.1 EN 60601-1 UL 60601-1 AS 3200.1.0* *Australian Deviation to IEC 60601-1	Device complies with the International Standard IEC 60601-1 CSA C22.2 No 601-1-M90 UL 2601
Electrical safety	Device complies with the International Standard CSA C22.2 No. 601-1-M90 UL 2601 Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1 Guidance, when applicable, has been adopted from the following standards: IEC 60601-2-25 IEC 60601-1-26 IEC 60601-2-40 IEC 60601-2-49	Device complies with the International Standard IEC 60601-1 IEC 60601-1-4 IEC 60601-1-26 CSA C22.2 No 601-1-M90 UL 2601

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Electromagnetic Compatibility (EMC)	Device complies with the following EMC standards IEC 60601-1 IEC 61000-4-2 IEC 61000-4-3 IEC 61000-4-6 Mil Std 462D IEC 61000-4-4 IEC 61000-4-5 EN55011 Class B Device complies with the requirements of Nov' 93 Draft Reviewer's Guidance	Device complies with the International Standard IEC 60601-1-2, including the following standards: CISPR 11 IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2, IEC 61000-4-3 IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11	Device complies with the International Standard IEC 60601-1- 2, including the following standards: IEC 61000-3-2 IEC 61000-3-3 IEC 61000-4-2 IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 IEC 61000-4-11 EN55011 class B EN55014-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2006

Regulatory Technology Services LLC
C/O Mr. Mark Job
Responsible Third Party Official
EB NEURO, S.P.A.
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K061996
Trade/Device Name: Sandman Pocket
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: September 22, 2006
Received: September 25, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

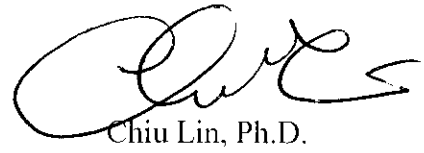
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Sandman Pocket

Indications For Use:

Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. The Sandman Pocket is indended for pediatric through adult patient populations, and can be used in either home or hospital environments.

The Sandman Pocket is not intended for use as life supporting equipment, such as a vital sign monitoring in on intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor.
The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...Number: K061996